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510(K) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes the Artimplant AB's summary for the Artelon™ Spacer CMC-I

SUBMITTER'S NAME:	Artimplant AB
ADDRESS:	Hulda Mellgrens gata 5, SE-421 32 Västra Frölunda, Sweden
CONTACT PERSON:	Britt Novén
TELEPHONE NUMBER:	+46 31 7465699 or +46 705 280255
FAX NUMBER:	+46 31 7465660
DATE OF SUBMISSION:	January 5, 2004

1. Identification of device

Proprietary Name: Artelon™ Spacer CMC-I
Common Name: Prosthesis, wrist, carpal trapezium
Classification Status: Class II per regulations §888.3770
Product Codes: KYI - Wrist joint carpal trapezium polymer prosthesis

2. Equivalent devices

The Artimplant Artelon™ Spacer CMC-I is substantially equivalent to the Avanta Orthopedics TRL Trapezium Soft Skeletal Implant (K964381)

3. Description of the Device

The Artelon™ Spacer CMC-I is a one-piece device intended to be implanted into the CMC-I joint and serve as an interpositional spacer between the trapezium bone and the first metacarpal bone.

It is composed of Artelon™, a polycaprolactone based poly(urethane urea), in multifilament form.

The Artelon™ Spacer CMC-I will be offered sterile.

4. Intended use

The Artelon™ Spacer CMC-I is intended to be implanted into the CMC-I joint as an interpositional spacer between the trapezium bone and the first metacarpal bone.

The device is intended to be used in thumb disabilities because of osteoarthritis.

5. Predicate device

Substantial Equivalence: The Artimplant Artelon™ Spacer CMC-I is substantially equivalent to the Avanta Orthopedics TRL Trapezium Soft Skeletal Implant (K964381).

6. Discussion of performance testing

A collection of tests has been conducted and successfully completed including safety and biocompatibility studies, tensile and compression tests and clinical evaluation in accordance to Artimplant's Quality System based on ISO 13485 and 21 CFR Part 820.

7. Discussion of Substantial Equivalence

Based on extensive technical and clinical performance testing and a comparison of the design and materials of the Artelon™ Spacer CMC-I to the predicate Avanta TRL Trapezium Implant, the Artelon™ Spacer CMC-I is substantially equivalent to the Avanta TRL Trapezium Implant (K964381) and presents no new concerns about safety and effectiveness. Additionally, the device has the same indications as the predicate device, and the labeling of the device is consistent with current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2004

Artimplant AB
C/o Ms. Marie Marlow
President and CEO
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

Re: K040070
Trade/Device Name: Artimplant AB, Artelon™ Spacer CMC-I
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: June 22, 2004
Received: June 23, 2004

Dear Ms. Marlow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040070

Device Name: Artimplant AB, Artelon™ Spacer CMC-I

Indications for Use:

The Artimplant Artelon® Spacer CMC-I The Artelon™ Spacer CMC-I is intended to be implanted into the first carpometacarpal joint as an interpositional spacer between the trapezium and first metacarpal.

The device is intended to be used in thumb disabilities because of osteoarthritis.

Prescription Use ___Yes___ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040070